

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA**

TAKEDA GMBH, ASTRAZENECA
PHARMACEUTICALS LP, and
ASTRAZENECA UK LIMITED,

Plaintiff,

v.

MYLAN PHARMACEUTICALS, INC.,

Defendant.

Civil Action No. 1:15-cv-00093

REPORT OF PARTIES' RULE 26(f) MEETING AND PROPOSED DISCOVERY PLAN

1. Pursuant to Fed. R. Civ. P. 16 and 26(f), Local Rule 16.01 (b) and (c), and the Court's August 10, 2015 order, Dkt. 20, the parties' counsel met by telephone on September 18, 2015, and October 5, 2015. The participants were:

- Amy K. Wigmore, Tracey C. Allen, Richard A. Crudo, and James F. Companion for Plaintiffs Takeda GmbH, AstraZeneca Pharmaceuticals LP, and AstraZeneca UK Limited (collectively, "Plaintiffs"); and
- Dennis Gregory, Nancy Zhang, Mary Procaccio-Flowers, and Gordon Copland for Defendant Mylan Pharmaceuticals, Inc. ("Mylan").

The parties discussed matters under Fed. R. Civ. P. 16 and 26(f), and Local Rule 16.01(b) and (c).

2. Pre-Discovery Disclosures

Plaintiffs' Position. The Court has established a deadline whereby the parties will exchange by October 21, 2015, the information required by Fed. R. Civ. P. 26(a)(1) and Local Rule 26.01(a). As set forth below, however, Plaintiffs believe that this case should be stayed in favor of a parallel proceeding pending in the District of New Jersey, at least until Mylan's pending motion to dismiss that case for lack of personal jurisdiction is decided, and that discovery across

all the related cases should proceed in a coordinated fashion. In any event, to the extent a case schedule is entered at this time, Plaintiffs respectfully request that the date for serving initial discovery disclosures be extended to November 17, 2015.

Defendant's Position.¹ Mylan believes that the Court-ordered October 21, 2015 deadline for the exchange of the information required by Fed. R. Civ. P. 26(a)(1) and Local Rule 26.01(a) should stand. As set forth in Mylan's Opposition to Plaintiffs' Motion to Stay filed July 31, 2015, a stay of this case is not appropriate and would unduly prejudice Mylan. Moreover, irrespective of a potential stay equivalent disclosures will happen in due course in the parallel District of New Jersey proceeding. Plaintiffs will not be prejudiced.

3. Discovery Plan

a. Background of Case. This is a patent infringement suit brought pursuant to the Hatch-Waxman Act. Plaintiffs have alleged that the product that is described in Mylan's Abbreviated New Drug Application ("ANDA") No. 208257—a generic roflumilast tablet in 500 mcg dosage strength ("Mylan's ANDA Product")—infringes one or more claims of Plaintiffs' U.S. Patent Nos. 5,712,298 (the "'298 patent"), 8,536,206 (the "'206 patent"), 8,604,064 (the "'064 patent"), 8,618,142 (the "'142 patent"). Plaintiffs sell roflumilast tablets under the tradename Daliresp® and have listed the '298, '206, '064, and '142 patents in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") in connection with its drug product. Mylan, in turn, has asserted counterclaims alleging that it does not infringe the claims of the '298, '206, '064, and '142 patents, and that the patents are invalid. Additionally, Mylan has asserted a declaratory judgment counterclaim alleging that Plaintiffs'

¹ Plaintiffs repeatedly use the parties' Joint Report of Rule 26(f) meeting and Proposed Discovery Plan as a vehicle to argue in support of their motion to stay. Mylan responds only to the extent necessary below.

U.S. Patent No. 8,431,154 (the “’154 patent”), which, at present, has not been asserted against Mylan, is not infringed and invalid. The ’154 patent is also listed in the FDA’s Orange Book in connection with Plaintiffs’ drug product. The ’298, ’206, ’064, ’142, and ’154 patents are referred to herein as the “patents-in-suit.”

b. New Jersey Action

Plaintiffs’ Position. As explained in Plaintiffs’ pending motion to stay, *see* Dkt. 13, this action should be stayed in its entirety in favor of a first-filed, substantively identical action involving the same parties and patents pending in the District of New Jersey. *See Takeda GmbH v. Mylan Pharm. Inc.*, No. 1:15-cv-00093 (D.N.J.). That action is just one of ten proceedings pending in the District of New Jersey that involve the patents-in-suit. Staying this action would conserve the Court’s and the parties’ resources by preventing two identical actions from proceeding in two separate forums and would eliminate the risk of inconsistent pretrial rulings.

Moreover, discovery in all the related actions should be coordinated. Issues such as the conduct of depositions of foreign witnesses, the translation of foreign-language documents, and document redaction protocols in accordance with European Union and German privacy laws will need to be negotiated. Similarly, requests for depositions are likely to overlap, and witnesses, particularly those residing outside of the United States, should not be burdened by having to sit for duplicative depositions. In the interest of efficiency and conservation of resources, it makes logical sense for Plaintiffs and all ten sets of defendants to negotiate a plan for dealing with these issues at one time in the context of a consolidated action, rather than piecemeal. The New Jersey court has set a status conference to address the issue of consolidation on October 20, 2015.

Defendant’s Position. Mylan does not believe this case should be stayed, as described above in Section 2. Mylan believes that the New Jersey court lacks personal jurisdiction over

Mylan. If Plaintiffs are truly concerned about coordinated pre-trial proceedings, other procedural options exist to remedy Plaintiffs' concerns. For example, they could dismiss this action.

c. Scope of Discovery. Discovery in that case will be needed on the issue of whether Mylan's ANDA Product infringes the claims of the patents-in-suit. Discovery will also be needed on the issue of whether the claims of the patents-in-suit are invalid, including the prosecution of the patents-in-suit, the conception and reduction to practice of the inventions of the patents-in-suit, and various objective indicia of non-obviousness, including whether there has been a failure of others, whether there has been a long-felt but unmet need, whether Daliresp® has been commercially successful, and whether the inventions of the patents-in-suit have any unexpected results.

Plaintiffs' Position. As set forth above, and as recognized by Mylan below, there are multiple unique discovery issues presented in this case that will be of concern to all of the parties in the related cases. As such, it makes sense that all affected parties address the issues in a coordinated fashion and not on a piecemeal basis.

Defendant's Position. Mylan expects that significant discovery may be required from the holder of the NDA for Daliresp® (roflumilast) Forest Research Institute Inc. ("Forest"). Plaintiffs have not yet definitively indicated whether Forest is obligated by agreement or otherwise to assist Plaintiffs in this litigation and whether Plaintiffs consider relevant Forest documents to be within their possession, custody, and control. Because Plaintiffs' ability to compel Forest to cooperate with discovery could significantly affect the time required to conduct fact discovery, Mylan proposes including a date certain for Plaintiffs to indicate (1) whether Forest is obligated by agreement or otherwise to assist Plaintiffs in Hatch-Waxman litigation and (2) whether Plaintiffs consider relevant Forest documents to be within their possession, custody, and control.

Mylan also expects significant foreign and foreign-language discovery in this case. Mylan understands that each of the seven named inventors of the patents-in-suit is German, at least one is deceased, and some or all of the remaining are no longer employed by Plaintiffs. Mylan therefore may need to proceed under the Hague Convention, which can lengthen the time required for fact discovery. Mylan proposes setting an early schedule for foreign depositions. Therefore, Mylan includes in its proposed schedule a date certain for Plaintiffs, for each living foreign inventor, to indicate whether (1) Plaintiffs can provide the inventor for deposition, or (2) Mylan will need to proceed under the Hague Convention.

Finally, Mylan understands that much of the work leading to the patents-in-suit took place in Germany, and therefore many potentially relevant documents are located in Germany and may need to be redacted due to that country's data privacy laws. In addition, Plaintiffs have indicated their willingness to negotiate a procedure for the production of translations. To solve these potential discovery issues, Mylan proposes that any case schedule entered include a date certain to agree to redaction and document translation production procedures.

d. Protective Order

Plaintiffs' Position. The parties will submit a proposed protective order to the Court addressing claims of confidentiality, privilege or protection as trial-preparation material asserted after production, in accordance with the proposed schedules below. A procedure applicable in the event that one of the parties wishes to assert a claim of confidentiality, privilege or protection after production will be included in any proposed protective order to be submitted to the Court.

Defendant's Position. Because Mylan already has served discovery requests pursuant to the schedule imposed by the Federal Rules, Local Rules, and the Court's order, Mylan believes a stipulated protective order should be negotiated and submitted soon, to the benefit of both parties.

Mylan proposes an early date for the submission of a proposed protective order to the Court.

However, to the extent the parties cannot agree, then Mylan proposes that Plaintiffs produce the IND and NDA on an “Outside Counsel’s Eyes Only” basis until the entry of a protective order.

e. Written Discovery and Depositions

i. Written Discovery

The Parties’ Position. Plaintiffs shall serve a maximum of 25 interrogatories (including all discrete subparts), and Defendant shall serve a maximum of 25 interrogatories (including all discrete subparts). Plaintiffs shall serve a maximum of 50 requests for admission, and Defendant shall serve a maximum of 50 requests for admission, exclusive of requests for admission solely for the purpose of authenticating documents.

ii. Depositions

Plaintiffs’ Position. Plaintiffs propose that Plaintiffs and Mylan shall each take a maximum of 10 fact depositions, unless this limit is increased by agreement of the parties or by order of the Court. Each deposition shall be limited to a maximum of 7 hours unless such maximum is increased by agreement of the parties or by order of the Court. Every 7 hours of deposition pursuant to a notice under Fed. R. Civ. P. 30(b)(6) shall count as one deposition.

Further, Plaintiffs disagree that there is a general need for two-day inventor depositions. To the extent that any such deposition must proceed in a language other than English, Plaintiffs are willing to meet and confer with Mylan to determine whether such deposition(s) warrant(s) additional time.

Defendant’s Position. Ten depositions is likely too few at least because this case involves three separate patent families with seven different named inventors. In addition, many depositions may need to proceed through interpretation with translated documents. Mylan

proposes that Plaintiffs and Mylan shall each take a maximum of 10 fact depositions, excluding inventor depositions, unless this limit is increased by agreement of the parties or by order of the Court. Each deposition, excluding inventor depositions, shall be limited to a maximum of 7 hours unless such maximum is increased by agreement of the parties or by order of the Court. Each inventor deposition shall be limited to a maximum of 14 hours unless such maximum is increased by agreement of the parties or by order of the Court. Each hour of deposition in a language other than English counts as half an hour of deposition. Regardless of length or the number of natural persons deposed, a deposition pursuant to a notice under Fed. R. Civ. P. 30(b)(6) shall count as one deposition. The parties should use their best efforts to minimize the burden placed on a party due to Rule 30(b)(6).

f. Supplementation. Supplementation under Fed. R. Civ. P. 26(e) shall be due within the time frames set in Fed. R. Civ. P. 26(e)(1) and Fed. R. Civ. P. 26(e)(2).

g. Bifurcation. The parties agree that discovery concerning the parties' claims of patent infringement and patent invalidity need not be conducted in phases, or be limited or focused to a particular issue.

h. Case Schedule

Plaintiffs' Position. As explained above and in their motion to stay, this action should be stayed in its entirety in favor of the pending New Jersey action. That action is just one of ten proceedings pending in the District of New Jersey that involve the patents-in-suit. Plaintiffs expect that the New Jersey actions will be consolidated. *See, e.g., Takeda GmbH v. Strides Pharma, Inc.*, No. 3:15-cv-03378, Dkt. 15 (D.N.J. July 27, 2015) (assigning single magistrate judge to handle all cases for pre-trial proceedings). A conference to address that issue has been set for October 20, 2015.

Further, as also explained in Plaintiffs' motion to stay, Mylan has filed a motion to dismiss for lack of personal jurisdiction in the first-filed New Jersey action. That motion has been fully briefed since July 27, 2015. *See Takeda GmbH v. Mylan Pharmaceuticals Inc.*, No. 3:15-cv-03384, Dkts. 12, 18, 26 (D.N.J.). Plaintiffs believe it is in the interest of efficiency to delay entering a schedule in this action at least until Mylan's motion to dismiss has been decided. In such case, entering a schedule in this action now would result in the needless expenditure of resources by the parties on discovery, that, as set forth above, Plaintiffs believe should be coordinated with parties in the related New Jersey cases. Thus, Plaintiffs respectfully request that the Court delay entering a schedule in this action at this time.

To the extent the Court believes a schedule should be entered, Plaintiffs propose the case schedule shown below.

Defendant's Position. As set forth in Mylan's Opposition to Plaintiffs' Motion to Stay filed July 31, 2015, a stay of this case is not appropriate and would unduly prejudice Mylan. There is no harm to Plaintiffs in proceeding with this action now, and Mylan does not believe that the Court should delay entering a schedule. As in any Hatch-Waxman litigation, the parties' time to litigate the matter is limited and it is in both parties' best interest to proceed.

Regardless of the outcome of the motion to stay or motion to dismiss, the parties will take discovery on these issues. Moreover, the parties agree the results of any discovery propounded in this litigation can be used in the parallel New Jersey proceeding.

Mylan's proposed schedule below is contingent upon the early resolution of discovery issues regarding the production of documents from the original NDA holder, the deposition availability of the six living German inventors of the patents-in-suit, the redaction of foreign language documents, and the production of translations.

Event	Plaintiffs' Proposed Deadline	Mylan's Proposed Deadline
Serve Initial Discovery Disclosures	November 17, 2015	October 21, 2015
Earliest date on which parties may begin serving discovery requests	December 3, 2015	September 18, 2015
Deadline for Plaintiffs to (1) indicate their access to documents from the original NDA holder, (2) for each living foreign inventor, indicate whether Plaintiffs can provide the inventor for deposition, or Mylan will need to proceed under the Hague Convention., and (3) propose procedures for production and potential redaction of foreign documents		October 26, 2015
Submission of proposed form of protective order to the Court	December 3, 2015	October 21, 2015
Submission to the Court of proposed ESI order to govern the discovery and production of ESI	December 3, 2015	October 21, 2015
Deadline to meet and confer regarding Plaintiffs' obligation to (1) indicate their access to documents from the original NDA holder, (2) for each living foreign inventor, indicate whether Plaintiffs can provide the inventor for deposition, or Mylan will need to proceed under the Hague Convention., and (3) propose procedures for production and potential redaction of foreign documents		November 6, 2015
Deadline to submit motions relating to Plaintiffs' obligation to (1) indicate their access to documents from the original NDA holder, (2) for each living foreign inventor, indicate whether Plaintiffs can provide the inventor for deposition, or Mylan will need to proceed under the Hague Convention., and (3) propose procedures for production and potential redaction of foreign documents		November 20, 2015
Plaintiffs' production of patents, IND, and NDA	December 17, 2015	November 20, 2015
Deadline for joining parties or amending pleadings	January 29, 2016	January 29, 2016
Identify claim terms for construction	January 15, 2016	January 15, 2016
Exchange proposed constructions	January 29, 2016	January 29, 2016

Event	Plaintiffs' Proposed Deadline	Mylan's Proposed Deadline
Submit Joint Claim Construction Chart	February 12, 2016	February 12, 2016
Opening claim construction briefs due	February 26, 2016	February 26, 2016
Responsive claim construction briefs due	March 25, 2016	March 25, 2016
Claim construction hearing	TBD by Court	TBD by Court
Substantial completion of document production	April 15, 2016	April 15, 2016
Close of fact discovery	August 26, 2016	August 26, 2016
Opening expert reports due	September 22, 2016	September 22, 2016
Rebuttal expert reports due	November 9, 2016	October 20, 2017
Reply expert reports due	December 16, 2016	November 10, 2016
Daubert motions	January 16, 2017	TBD
Responsive Daubert Motions	January 30, 2017	TBD
Close of expert discovery	February 23, 2017	December 9, 2016
Dispositive motions due	March 23, 2017	January 6, 2017
Opposition to dispositive motions	April 20, 2017	February 3, 2017
Replies to dispositive motions	May 4, 2017	February 17, 2017
Motions in limine	May 18, 2017	April 24, 2017
Joint pretrial order due	May 25, 2017	One week before the pre-trial conference
Responses to motion in limine	May 28, 2017	May 8, 2017
Final pretrial conference	June 2017	One week before trial
Trial	July 2017	May 22, 2017

4. Preservation and Discovery of Electronically Stored Information (“ESI”)

At this time, the parties do not anticipate any issues regarding the preservation of ESI.

Plaintiffs’ Position. On the date the Court sets as the earliest date on which the parties may begin serving discovery, the parties will submit a proposed ESI order to govern the discovery and production of ESI.

Defendant’s Position. Concurrent with their submission of the proposed protective order, October 21, 2015, the parties will submit a proposed ESI order to govern the discovery and production of ESI.

5. Other Items

In the event this case proceeds, Plaintiffs believe that this case will be ready for trial by July 2017. Mylan believes that this case will be ready for trial by May 22, 2017. The parties estimate that trial will take one to two weeks.

The parties do not consent to trial by a magistrate judge.

The parties do not believe that this case is complex and requires case-management conferences.

Other than the admissions contained in Mylan’s answer to Plaintiffs’ complaint and Plaintiffs’ reply to Mylan’s counterclaims, the parties are unable to agree upon disputed facts that have been alleged with particularity in the pleadings. The parties will continue to discuss whether they can agree upon the disputed facts that have been alleged in the pleadings.

The parties have not discussed settlement at this stage. The parties do not believe that alternative dispute resolution processes will further prospects for settlement at this time.

With respect to an agenda on matters to be discussed at the scheduling conference, the parties will be prepared to discuss the proposed case schedule and discovery plan.

Respectfully submitted,

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